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**TRANSMITTAL FORM**

(for all correspondence after initial filing)

<b>TRANSMITTAL FORM</b> (for all correspondence after initial filing)	Application #	10/622,803
	Confirmation #	3480
	Filing Date	July 21, 2003
	First Inventor	BERTAGNOLI
	Art Unit	3733
	Examiner	Reimers, Annette R.
Total number of pages in this submission =	Docket #	P07878US00/MP

**ENCLOSURES** (check all that apply)

<input type="checkbox"/> Fees calculated below	<input type="checkbox"/> Reply to Missing Parts/Incomplete Application
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Certified Copy of Priority Document(s)
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<input type="checkbox"/> <b>After Final</b> Amendment/Reply	<input type="checkbox"/> Drawing(s)
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<input type="checkbox"/> Extension of Time Petition	<input checked="" type="checkbox"/> Response to Notification of Non-Compliant Appeal Brief (37 CFR 41.37)
<input type="checkbox"/>	<input checked="" type="checkbox"/> Amended Appeal Brief Under 37 C.F.R. § 41.37

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- ☒ The Director is authorized to charge any fee, additional fee or extension fee due in connection herewith to Deposit Account No. 12-0555:
- (1) if no payment or an insufficient payment is enclosed and a fee is due in connection herewith; or
- (2) if no petition for extension of time is enclosed but an EOT is required - and in this event, applicant hereby petitions under 37 CFR 1.136(a) for an extension of time of as many months as are required to render this submission timely.

Date: February 1, 2008

  
Signed By Name: Marvin Petry  
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**RESPONSE TO  
NOTIFICATION OF  
NON-COMPLIANT APPEAL  
BRIEF (37 CFR 41.37)**

Application #	10/622,803
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Commissioner for Patents  
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Alexandria, VA 22313-1450

S I R:

In response to the Notification of Non-Compliant Appeal Brief of January 22, 2008, Applicants submit the following Amended Appeal Brief. Applicants respectfully submit that the Amended Appeal Brief is in full compliance with the requirements of 37 C.F.R. § 41.37 and respectfully provide the following discussion as follows.

In the Notification of Non-Compliant Appeal Brief Part 4, it was indicated that the brief did not contain a concise explanation of the subject matter defined in each independent claim and/or the brief fails to identify each independent claim on appeal, and/or set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line and the drawings, if any, by reference characters. In the Amended Appeal Brief, Applicants have supplemented the Appeal Brief by referring specifically to reference characters in the drawings of record and further supplemented portions of the specification which support the subject matter of the claims on appeal. Accordingly, Applicants respectfully submit that the present Amended Appeal Brief is in full compliance with the requirements of 37 C.F.R. § 41.37(c)(1)(v).

In Part 5, it was indicated that the brief does not contain a concise statement of each ground of rejection presented for review citing 37 C.F.R. § 41.37(c)(1)(vi).

Applicants in response respectfully submit that the brief does contain a concise statement of the sole ground of rejection presented for review is presented in the Appeal Brief under heading VI.1. Accordingly, Applicants respectfully submit that the Appeal Brief is in compliance with the requirements of 37 C.F.R. § 41.37(c)(1)(vi).

In Part 6 of the Notification, it was indicated that the brief did not present an argument under a separate heading for each ground of rejection on appeal. Applicants respectfully submit that the brief in accordance with 37 C.F.R. § 41.37(c)(1)(vii) contains an argument under the heading VII.B. for the sole ground of rejection on appeal in accordance with 37 C.F.R. § 41.37(c)(1)(vii).

In Part 10 of the Notification, it was indicated that the claims contain claims that are withdrawn, namely claims 4, 13, 14, 19-21, 26-28, 31, 32 and 35. However, it was alleged that the claims were not presented for appeal and they do not need to be presented in the claims listed under appeal. In response, Applicants respectfully submit that the withdrawn claims 4, 13, 14, 19-21, 26-28, 31, 32 and 35 are species of the generic invention recited in claim 1 and therefore, upon finding claim 1 allowable, the withdrawn claims should be found allowable as being species claims which include the subject matter of what should be found allowable generic claim 1 in accordance with the requirements of 37 C.F.R. §§ 1.141 and 1.146. This point has been made in the Appeal Brief in Section VII.C. It should be noted that consideration of the withdrawn species claims has not been indicated as a grounds of rejection to be reviewed on appeal as the issue of consideration of the withdrawn species claims is not ripe until generic claim 1 is found to be allowable. However, to preserve the right to have the withdrawn claims

considered and for economic conservation, the request for consideration has been raised in the Appeal Brief and accordingly are included in the claims on appeal.

Further, in Part 10, it was noted that "Applicant should also make clear the summary of claimed subject matter by adding reference numbers to the drawings, if applicable." By this amendment, Applicants have supplemented the Amended Appeal Brief with identification of the claimed elements using the reference numbers of the drawings in the application.

In addition, in Part 10, it was stated "Further, applicant has provided separate summaries for the claims and dependent claims, but has not provided separate arguments for all of these points." In response, Applicants respectfully submit that there is no specific requirement that each and every claim including all dependent claims be argued separately. See, e.g., 37 C.F.R. § 41.37(c)(1)(vii). It will be readily apparent to the Appeal Board, based on the arguments presented, that it is unnecessary to argue each claim limitation over each dependent claim separately in view of the arguments of non-obviousness presented in the Appeal Brief. Accordingly, Applicants respectfully submit that the Arguments section is in full compliance with the requirements of 37 C.F.R. § 41.37(C)(1)(vii).

Finally, in Part 10, it was noted that "the MPEP requires that the IX. Evidence Appendix and X. Related Proceedings Appendix be on SEPARATE PAGES." In response, Applicants respectfully submit that 37 C.F.R. § 41.37 does not require a separate page for Parts IX. and X. of the Appeal Brief. Although MPEP § 1205.02 suggests that Sections IX. and X. should appear on a separate page, there is no such requirement in the patent laws under 35 U.S.C. or 37 C.F.R. Furthermore, as noted in

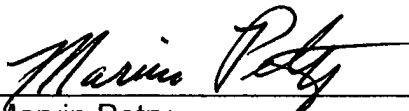
the Appeal Brief, Applicants are not submitting any evidence under Parts IX. and X as indicated. Therefore using the appropriate designation, "NOT APPLICABLE."

Applicants in complete compliance with the requirements of 37 C.F.R. § 41.37(c)(1)(ix) and (x) present the Appeal Brief with Parts IX. and X. on a single sheet of paper.

In view of the foregoing, Applicants respectfully submit that the present Amended Appeal Brief is in full compliance with the requirements of 37 C.F.R. § 41.37.

Respectfully submitted,

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February 1, 2008



**AMENDED APPEAL BRIEF  
UNDER  
37 C.F.R. § 41.37**

Application #	10/622,803
Confirmation #	3480
Filing Date	July 21, 2003
First Inventor	BERTAGNOLI
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Commissioner for Patents  
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**APPEAL FROM THE FINAL REJECTION  
MAILED MARCH 26, 2007**



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RUDOLFO BERNARDI (hereinafter "Appellant"), by and through his attorney,  
hereby submits this appeal brief pursuant to 37 C.F.R. § 41.37.

**I. REAL PARTY IN INTEREST**

Spine Solutions, Inc. is the real party in interest.

**II. RELATED APPEALS AND INTERFERENCES**

There are no related appeals or interferences.

**III. STATUS OF CLAIMS**

The application contains a total of thirty-one claims, claims 1-14 and 19-35. Claims 1-3, 5-12, 22-25, 29, 30, 33 and 34 have been rejected and claims 4, 13, 14, 19-21, 26-28, 31, 32 and 35 have been withdrawn from consideration. Claims 1-14 and 19-35 are appealed.

**IV. STATUS OF AMENDMENTS**

The claims filed in the Amendment of March 7, 2006 represent the pending claims on appeal.

**V. SUMMARY OF CLAIMED SUBJECT MATTER**

Appellant's presently claimed invention is directed to a unique instrument for separating at least two vertebrae and/or retaining at least two adjacent vertebrae in a spaced apart condition. The instrument, as recited in claim 1, comprises a plurality of anchor screws, each having a forward end securable to a vertebrae and a rear end



remote therefrom. (Present specification, ¶¶ [0006]-[0008], [0029], [0030].) A frame member comprises at least two arms, each arm having a tube at least in part encircling one of the anchor screws. (Present specification, ¶¶ [0029]-[0033].) Retaining screws secure each of the anchor screws to their respective tubes. (Present specification, ¶ [0033].)

Referring to one embodiment disclosed in the specification and depicted in Figures 1-4 and 6-8, for educational purposes only in order to illustrate one possible embodiment in accordance with the claimed invention, with regard to claim 1, a plurality of anchor screws 35 (Figures 1 and 3), each have a forward end (threaded end 38), securable to a vertebrae (V1, V2; Figure 1), and a rear end remote therefrom (the end proximate threads 39, Figure 3). A frame member (5, Figure 1), comprises a pair of arms (first arm 11, second arm 12; Figure 1). Each arm (11, 12), has a tube (19, 23; Figure 1) at least in part encircling one of the anchor screws (35) and a connecting member (toothed rod 13, Figure 1) connecting the arms (11, 12) for movement of the arms (11, 12) towards and away from each other. A retaining structure (retaining nut 40, Figures 1, 4) secure each of the anchor screws (35, Figures 1, 3), to its respective tube (19, 23; Figure 1). (Present specification paragraphs [0006]-[0008], [0029]-[0033].)

Referring specifically to claim 22, with exemplary reference to elements of a preferred embodiment for educational purposes only, and in no way to limit the scope of the claimed invention in any way, the instrument (5; Figure 1) comprises a plurality of anchor screws (35, Figures 1 and 3), each having a forward end (and proximate threads 38; Figure 3) securable to a vertebrae (V1, V2; Figure 1) and a frame

member (5; Figure 1) comprising at least two arms (11, 12; Figure 1) and a connecting member (13; Figure 1) operatively connecting the two arms (11, 12; Figure 1) for movement toward and away from each other. (Present specification, ¶¶ [0029]-[0030].) Each of the arms (11, 12; Figure 1) have an engaging structure (e.g., hollow tubes 19, 23; Figure 1) operatively associated with one of the anchor screws (35; Figure 1). (Present specification, ¶ [0030].) Each arm (11, 12; Figure 1) further includes a retaining structure (e.g., nut 40; Figures 1 and 4) operatively securing the engaging structure (19, 23; Figure 1) of each arm (11, 12; Figure 1) with its respective anchor screw (35; Figure 1) to essentially prevent movement of the anchor screw (35; Figure 1) relative to its engaging structure (19, 23; Figure 1). (Present specification, ¶ [0033].)

Novelty, in part, of the present instrument over prior instruments lies in a retaining structure which secures each anchor screw to a respective arm of the instrument. Thus, the present instrument attaches securely to the part which the instrument is manipulating. (Present specification, ¶ [0037].) Advantageously, the anchor screws are secured to the instrument so that there is essentially no movement of the anchor screws relative to the insertion tool. (Present specification, ¶¶ [0005], [0007], [0009], [0037].)

The present retaining structure arrangement is in direct contrast to prior instruments in this art, in which prior instruments are not securely fastened to the part which the instrument is manipulating. (See, e.g., present specification, ¶ [0004].) Moreover, prior instruments are designed to slidably engage with a part to allow easy, quick attachment and release and, accordingly, the part is not secured to the

instrument. (Present specification, ¶ [0004].) However, unlike conventional instruments, the part manipulated by the instrument is secured to the instrument via the anchor screws. (Present specification, ¶ [0006].) The retaining structure essentially prevents movement of the anchor screws relative to the frame of the instrument. (Present specification, ¶ [0009].) As a result, the anchor screws maintain their original alignment with the frame, and thus prevent any misalignment which might cause the instrument to jam during use. (See, e.g., present specification, ¶¶ [0004], [0006]-[0008], [0035]-[0038].)

Referring to a preferred embodiment described in the present specification, as shown in Figure 1, a retaining structure is provided in the form of retaining nuts 40 which are screwed down onto threaded ends of anchor screws 35 which project up through the open ends of the tubes 19 and 23. (Present specification, ¶ [0035]). Referring to Figure 3, one exemplary anchor screw is depicted as anchor screw 35 having a threaded end 38 for driving the screw into a vertebrae and a threaded end 39 to which a retaining nut 40 has threads which match. (Present specification, ¶ [0033].) In using the present instrument, a pair of anchor screws 35 are first screwed into adjacent vertebrae, e.g., V1 and V2. (Present specification, ¶ [0037].) After both anchor screws have been screwed into the vertebrae V1 and V2, a frame 10 is brought over the anchor screws with the tubes 19 and 23 encircling the anchor screws 35. (Present specification, ¶ [0037].) Retainer nuts 40 are then screwed onto the exposed threaded ends 39 to securely tighten the retainer nuts 40 and thereby securely tighten the anchor screws 35 within respective tubes 19 and 23. (Present specification, ¶ [0037].) At this point, the anchor screws and the frame 10 form a very secure, tight,

unitary unit. (Present specification, ¶ [0037].) Using the unitary unit, one is ready for movement of the arms 11 and 12 away from each other to distract the vertebrae V1 and V2. (Present specification, ¶ [0038].)

In an alternative retaining structure to the one shown in Figure 1, in which retaining nuts 40 are screwed down onto threaded ends of the anchor screws 35, Figure 10, instead of projecting up through the open ends of tubes 19 and 25, the tubes themselves, 19', 25', have enlarged openings for receiving retaining structures below the upper ends thereof. (Present specification, ¶ [0035].) The anchor screw 50 terminates within the enlarged openings for receiving retaining structures below the upper ends thereof. (Present specification, ¶ [0035].) Figure 10 also illustrates schematically another variation of a suitable retaining structure in the form of retaining structure 51, as a resilient cap or cap which engages the top of the anchor screw with a bayonet-type joint. (Present specification, ¶ [0035].)

For exemplary purposes only to help illustrate one possible form of the claimed invention, but not to limit the scope of the claimed invention in any way, discussion of the claim subject matter of claims 1-34 are provided with reference to one preferred embodiment.

Referring now specifically to the subject matter of claim 1, claim 1 recites an instrument comprising a plurality of anchor screws (35; Figure 1), each having a forward end (e.g., proximate threads 38, Figure 3) securable to a vertebrae (V1, V2; Figure 1) and a rear end remote therefrom (e.g., proximate threads 39, Figures 1, 3). (Present specification, ¶¶ [0006]-[0008], [0029], [0030].) A frame member (5; Figure 1) comprises at least two arms (11, 12; Figure 1), each arm having a tube (19, 23;

Figure 1) at least in part encircling one of the anchor screws (35; Figures 1, 3).

(Present specification, ¶¶ [0029]-[0033].) Retaining screws (40; Figures 1, 3) secure each of the anchor screws (35; Figures 1, 3) to their respective tubes (19, 23; Figure 1). (Present specification, ¶ [0033].)

Claims 2-21 further define characteristics of the present instrument. For example, claim 2 recites that the retaining structure (40; Figures 1, 4) for each anchor screw (35; Figures 1, 3) engages the rear end of the anchor screw (proximate threads 39; Figure 3) and securely tightens it against the rear end (proximate nut 40; Figure 1) of the tube. (Present specification, ¶ [0033].)

Claim 3 depends from claim 2 and further recites that the rear end (proximate threads 39; Figure 3) of each anchor screw (35, Figure 3) is threaded (e.g., threads 39; Figure 3) and the retaining structure comprises a threaded nut (40; Figures 1, 4) which threadingly engages the rear end of the anchor screw. (Present specification, ¶ [0037].)

Claim 5 recites the instrument of claim 1, wherein the connecting member (13; Figure 1) comprises a connecting bar (13; Figure 1) having two telescopic members (13, 14; Figure 1), one arm (11, 12; Figure 1) connected to each of the telescopic members (13, 14; Figure 1), such that the telescopic movement of one of the telescopic members relative to the other causes the arms (11, 12; Figure 1) to move toward and away from each other. (Present specification, ¶ [0030].)

Claim 6 depends from claim 5 and further recites the inner (13; Figure 1) of the two telescopic members being a toothed rod and the outer (14; Figure 1) of the two telescopic members having a toothed wheel (26; Figure 1) fixed thereto which engages

the toothed rod (13; Figure 1) for moving the two telescopic members (13, 14; Figure 1) relative to each other. (Present specification, ¶¶ [0030]-[0032].)

Claim 7 depends from claim 6 and further recites a releasable catch (e.g., lever 31 with tip 32; Figures 6-7) mounted on the outer (14; Figures 1, 6, 7) of the telescopic members, which catch engages the teeth (15; Figure 6) on the inner of the telescopic members (e.g., rod 13; Figure 6) for permitting free movement of the two telescopic members relative to each other in one direction but stopping movement of the two telescopic members relative to each other in the other direction. (Present specification, ¶ [0032].)

Claim 8 depends from claim 1 and further recites that two anchor screws (35; Figures 1, 3) are securable to adjacent vertebrae (V1, V2; Figure 1), the frame member (5; Figure 1) has a pair of arms (11, 12; Figure 1), and each arm has a tube (19, 23; Figure 1) encircling at least one of the anchor screws. (Present specification, ¶ [0037].)

Claim 9 depends from claim 8 and further recites that the retaining structure engages the rear end (proximate threads 39; Figure 3) of its anchor screw (35; Figure 3) and tightly engages the rear end of the tube (19, 23; Figure 1). (Present specification, ¶ [0037].)

Claim 10 depends from claim 9 and recites that the connecting member (13, 14; Figure 1) comprises two telescopic members (13, 14; Figure 1), one arm (11, 12; Figure 1) connected to each of the telescopic members, such that the telescopic movement of one of the telescopic members relative to the other causes the arm to move toward and away from each other. (Present specification, ¶ [0030].)

Claim 11 depends from claim 10 and recites a releasable catch (e.g., lever 31; Figures 6-7) mounted on the outer (14; Figures 1, 6, 7) of the telescopic members, in which the releasable catch engages the teeth (15; Figure 6) on the inner (13; Figures 6, 7) of the telescopic members for permitting free movement of the two telescopic members relative to each other in one direction, but stops movement of the two telescopic members relative to each other in the other direction. (Present specification, ¶¶ [0030]-[0032].)

Claim 12 depends from claim 1 and recites the connecting member is a bar member (13, 14; Figure 1) and the two arms move along the bar. (Present specification, ¶¶ [0008], [0030].)

Claim 22 is an independent claim which recites an instrument for spreading at least two adjacent vertebrae and/or retaining at least two adjacent vertebrae in a spaced apart condition. The instrument (5; Figure 1) includes a plurality of anchor screws (35; Figure 3), each having a forward end (proximate threads 38; Figure 3) securable to a vertebrae (V1, V2; Figure 1) and a frame member comprising at least two arms (11, 12; Figure 1) and a connecting member (13, 14; Figure 1) operatively connecting the two arms for movement toward and away from each other. Each of the arms (11, 12; Figure 1) have an engaging structure (e.g., hollow tubes 19, 23; Figure 1) operatively engagable with one of the anchor screws. Each arm further includes a retaining structure (nut 40; Figures 1, 4) operatively securing the engaging structure of each arm with its respective anchor screw to essentially prevent movement of the anchor screw relative to its engaging structure. (See, e.g., present specification, ¶ [0036].)

Claim 23 depends from claim 22 and recites that the engaging structure (e.g., tubes 19, 23; Figure 1) of each arm includes a part encircling its respective anchor screw. (Present specification, ¶ [0036].)

Claim 24 depends from claim 23 and recites that the retaining structure (40; Figure 1) engages its respective anchor screw on the side of the encircling part remote from the vertebrae (e.g., proximate threads 39; Figure 3). (Present specification, ¶¶ [0034]-[0037].)

Claim 25 depends from claim 24 and recites that the retaining structure is a threaded nut (e.g., 40; Figure 1) engagable with a threaded part of the anchor screw. (Present specification, ¶ [0037].)

Claim 29 depends from claim 22 and recites that the retaining structure (e.g., nut 40; Figure 1) engages its anchor screw (35; Figure 3) at an end thereof opposite from its end connected to the vertebrae. (Present specification, ¶ [0037]; Figure 1.)

Claim 33 depends from claim 22 and recites that the connecting member comprises a connecting bar having two telescopic members (13, 14; Figure 1), one arm (11, 12; Figure 1) connected to each of the telescopic members, such that telescopic movement of one of the telescopic members relative to the other causes the arms to move toward and away from each other. (Present specification, ¶ [0030]; Figure 1.)

Claim 34 depends from claim 22 and further recites two anchor screws (35; Figure 3) securable to adjacent vertebrae (V1, V2; Figure 1), the frame member having a pair of arms (11, 12; Figure 1), each arm having an engaging structure (e.g., hollow



tubes 19, 23; Figure 1)engaging one of the anchor screws (35; Figure 3). (Present specification, ¶ [0037].)

## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

1. Claims 1-3, 5-12, 22-25, 29, 30, 33 and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolger et al. (U.S. Patent No. 6,770,096) (hereinafter “Bolger”) in view of Martin Benlloch et al. (U.S. Patent No. 6,676,661) (hereinafter “Benlloch”).

## **VII. ARGUMENT**

### **A. INTRODUCTION**

The present instrument is a unique tool which includes a retaining structure for securing each of the anchor screws to a respective tube which, at least in part, encircles one of the anchor screws. Accordingly, the present instrument uniquely forms a unitary structure with the part which the instrument is to manipulate, namely the anchor screws. Thus, unlike conventional manipulating instruments which attach to a part to be manipulated, but are not securely fastened, the present instrument distinguishes itself over prior instruments.

Furthermore, the present instrument overcomes a disadvantage in the instrument art in which prior instruments are not securely fastened to the anchor screws and, as a result, the prior instruments tended to become misaligned due to the anchor screws being loosely held in place in a frame of the prior art instruments.

Appellant respectfully submits that it will be clear from the following discussion that the appealed claims, 1-3, 5-12, 22-25, 29, 30, 33 and 34, should be found to be

allowable. Further, Appellant submits that the non-elected claims, 4, 13, 14, 19-21, 26-28, 31, 32 and 35, should be rejoined and found allowable, as depending directly or indirectly from one of the claims which should be found now allowable.

**B. CLAIMS 1-3, 5-12, 22-25, 29, 30, 33 AND 34 ARE NOT  
OBVIOUS UNDER 35 U.S.C. § 103(a) AS BEING  
UNPATENTABLE OVER BOLGER IN VIEW OF BENLLOCH**

Appellant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness of the claims in view of the cited prior art. Further, Appellant respectfully submits, notwithstanding the failure to establish a *prima facie* case of obviousness, that there fails to be any reasonably apparent reason for one of ordinary skill in the art to combine the teachings of Bolger with Benlloch to make the presently claimed instrument obvious.

**1. THE EXAMINER HAS FAILED TO ESTABLISH A  
PRIMA FACIE CASE OF OBVIOUSNESS OF CLAIMS 1-3,  
5-12, 22-25, 29, 30, 33 AND 34 UNDER 35 U.S.C. § 103(a)  
FROM BOLGER IN VIEW OF BENLLOCH**

The Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a) from Bolger in view of Benlloch. Specifically, the Examiner has failed to allege why one of ordinary skill in the art would have been led to combine the teachings of Bolger with Benlloch. Further, the Examiner has failed to establish any facts which would lead a person of ordinary skill in the art to combine the manipulation instrument of Bolger with the anchor bolt and nut of Benlloch.

To establish a *prima facie* case of obviousness, there must be more than a demonstrated evidence of all components of the claimed subject matter present in one or more prior art references. There must be some reason for the combination whereby a person of ordinary skill in the prior art would make the substitutions or modifications

required in the present invention. The reason for the combination can be in the form of a recognized problem in the art which the combination solves. (See *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_\_ (2007). However, the knowledge of a recognized problem or reason for the combination cannot come from the Applicant's disclosure of the invention itself. (See, *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); *In re Geiger*, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985), *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992)).

Turning to the prior art which is the subject of the outstanding rejections of the claims, Bolger is specifically directed to a spinal stabilization cage which is disposed between two adjacent vertebrae and is anchored to allow no degree of freedom (see, e.g., Bolger, column 2, lines 35-45 and column 4, lines 18-46). The Bolger device is similar to prior art devices described in the present specification, e.g., paragraph [0004]. As with similar prior art instruments, the Bolger instrument slidably engages with anchoring screws or rods inserted into adjacent vertebrae to allow the separation during insertion of the anchor means and, after the anchor means is attached, to slidably remove the instrument from the anchor screws.

Although, the anchoring rods of Bolger may appear to be held tightly by the frames, in fact, the Bolger device has a loose engagement, as compared with a very secure engagement of the present invention. Consequently, the relatively loose engagement of Bolger will cause the anchor screws to become misaligned. As a result, the device of Bolger may become jammed, resulting in the instrument not performing its

intended function of separating adjacent vertebrae. Nowhere in Bolger is there any identification of any problem with its device, a lack of secure engagement between the instrument and the anchor screws, or any desire to provide a more secure engagement between the instrument and the anchoring screws.

Benlloch discloses a connecting rod (1) with threaded ends for permanently attaching a connecting element (4) to a vertebrae. (Benlloch, Figures 1-3 and column 2, line 44-column 3, line 3.) Benlloch is specifically directed to affixing a permanent spinal implant in a patient using a nut (9) which is tightened down on the threaded end of rod (1), which has been inserted into a vertebrae through bore (10) (Benlloch, Figure 1). Thus, the Benlloch disclosure is limited to a spinal implant. Benlloch fails to disclose any insertion tool or instrument for inserting the tool or connector in a patient. Furthermore, the disclosure of Benlloch is limited to permanently securing an implant in place on the spinal column of a patient.

The Examiner has failed to allege any facts or in any way substantiate why one of ordinary skill in the art would have found it obvious to combine Bolger and Benlloch to make the present invention obvious. To the contrary, the Examiner has provided only a conclusionary statement:

It would have been obvious to one skilled in the art at the time the invention was made to construct the distraction device of Bolger et al. with a retaining structure for securing each of the anchor screws to its respective tube, wherein the retaining structure engages the rear end of the anchor screw and securely tightens it against the rear end of the tube, and wherein the retaining structure comprises a threaded nut, which threadedly engages the rear end of the anchor screw, in view of Martin Benlloch et al., in order to immobilize the screw in terms of rotation.

(Office Action, March 26, 2007, page 5.)

The Examiner has failed to allege a single fact which would support such a conclusion, i.e. that one of ordinary skill in the art would have found it obvious to immobilize an anchor screw to a manipulating instrument. For example, the Examiner has failed to establish any facts supporting why one of ordinary skill in the art would find it necessary to immobilize the anchor screws of the instrument. Further, the Examiner has failed to identify any reason why one of ordinary skill in the art would modify the manipulation instrument of Bolger to have the retaining means of Benlloch secure the anchor screws to the manipulation instrument. Furthermore, the Examiner has failed to identify any problem which would have been known to one of ordinary skill in the art, save the present specification, which would lead one of ordinary skill in the art to combine the retaining means of Benlloch with the instrument of Bolger. Although the Examiner states: "It is well known in the art that threaded nuts are used as retaining structures for screws" (Office Action, March 26, 2007), the Examiner has failed to provide any facts which would support why one of ordinary skill in the art would use threaded nuts for retaining the anchor screws of Bolger in a secure condition to its manipulation instrument. Furthermore, the Examiner has failed to provide any evidence that one of ordinary skill in the art would have recognized a problem with the device of Bolger which would lead one of ordinary skill in the art to secure the anchor screws to the instrument.

**2. THERE FAILS TO BE ANY REASON FOR A PERSON  
HAVING ORDINARY SKILL IN THE ART TO COMBINE THE  
DEVICE OF BOLGER WITH THE DEVICE OF BENLLOCH**

Notwithstanding the Examiner failing to establish a *prima facie* case of obviousness, there fails to be any reason for a person having ordinary skill in the art to combine the instrument and rods of Bolger with the retaining nut of Benlloch. In order

for two references to be combined in an obviousness-type rejection under 35 U.S.C. § 103(a), there must be “a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements” in the manner claimed. *KSR Int’l. Co. v. Teleflex Inc.*, 550 U.S. \_\_\_\_ (2007), Slip Opinion at page 14. Although the Examiner has alleged that it would have been obvious to combine the references in order to immobilize a screw in terms of rotation, nowhere in the art, let alone the references, is there any teaching of a problem or any desire to limit the rotation of the tool relative to the anchor screw. Accordingly, such a conclusion has no basis in the art, let alone in the cited prior art of record.

Moreover, Bolger is completely silent with regard to any rationale or acknowledgment why one would wish to temporarily securely fasten the rods to the frame of the instrument. Accordingly, the cited prior art, as well as the art in general, fails to appreciate any problem with the engagement of the anchor screws with their instruments, fails to identify any problem associated with the engagement of the anchor screws with their instruments and, therefore, fails to provide any reason for one of ordinary skill in the art to modify its instrument to include a retaining structure for securing the anchor screws to their respective instruments.

Furthermore, as acknowledged in the present specification, and as is ubiquitous in the prior art as evidenced by Bolger, the presence of threadings on anchor bolts, connecting rods and the like, and the use of nuts attached thereto, does not in any way provide a reason for one of ordinary skill in the art to use attachment means to temporarily secure an implant to an insertion tool. The prior art fails to provide any reason for one of ordinary skill in the art to make such a modification or to prompt one of

ordinary skill in the art in the relevant field to combine the insertion instrument and rods of Bolger with the retaining bolts of Benloch in the manner claimed. It is only through an identification of there being a problem with the prior art instruments and, in particular, the loose engagement of the instrument with the anchor screws, as discussed in the present specification, that one of ordinary skill in the art would have any reason to securely fasten the anchor screws to the frame of the insertion instrument.

**3. THE PRESENT INSTRUMENT FILLS A LONG FELT  
NEED IN THE ART, THUS ESTABLISHING SECONDARY  
CONSIDERATIONS OF NON-OBVIOUSNESS**

Prior to the present invention, insertion tools, as well as tools in general, were not temporarily securely fastened to the part which the instrument was manipulating. In this regard, the present insertion instrument is unique. Further, it would have been counterintuitive to temporarily secure the anchor screws to the manipulation instrument, only to have to remove the securing means to remove the instrument from the anchor screws. Furthermore, the secure fastening of the anchor screws to the frame provides a unitary unit which fills a void in the art in terms of a long felt need for a superior insertion tool, thus establishing secondary considerations of non-obviousness.

**C. WITHDRAWN CLAIMS 4, 13, 14, 19-21, 26-28, 31, 32  
AND 35 ARE ALLOWABLE OVER THE PRIOR ART**

Claims 4, 13, 14, 19-21, 26-28, 31, 32 and 35 should be rejoined in the present application. Independent claim 1 is generic to all pending claims including the withdrawn claims 4, 13, 14, 19-21, 26-29, 31, 32 and 35. Therefore, in accordance with 37 C.F.R. § 1.141(a), the present application only includes claims to a single independent and distinct invention. In view of the discussion above, these withdrawn claims depend from what should be found to be allowable claims. Hence, all withdrawn

claims include the subject matter of generic allowable claim 1. Accordingly, the previously withdrawn claims should be rejoined in the present application, and moreover, found allowable as being novel and non-obvious over the prior art for at least the same reasons as the non-withdrawn claims discussed above.

**D. SUMMARY AND CONCLUSION**

In view of the above, it is respectfully submitted that the appealed claims are novel and non-obvious. The Examiner's rejections should be **REVERSED**.

Date: February 1, 2008

Respectfully submitted,



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## **VIII. CLAIMS APPENDIX – CLAIMS ON APPEAL**

1. An instrument for spreading at least two adjacent vertebrae and/or retaining at least two adjacent vertebrae in a spaced apart condition, comprising:

a plurality of anchor screws, each having a forward end securable to a vertebrae and a rear end remote therefrom,

a frame member comprising at least two arms, each arm having a tube at least in part encircling one of the anchor screws, and a connecting member connecting the arms for movement of the arms toward and away from each other, and

a retaining structure for securing each of the anchor screws to its respective tube.

2. An instrument according to claim 1, the retaining structure for each anchor screw engaging the rear end of the anchor screw and securely tightening it against the rear end of the tube.

3. An instrument according to claim 2, wherein the rear end of each anchor screw is threaded, and the retaining structure comprises a threaded nut which threadedly engages the rear end of the anchor screw.

4. (Withdrawn) An instrument according to claim 2, wherein the rear end of each anchor is located in a recess formed in the top of its respective tube, and the retaining structure is also located in said recess.

5. An instrument according to claim 1, wherein the connecting member comprises a connecting bar having two telescopic members, one arm connected to each of said telescopic members, such that telescopic movement of one of the telescopic members relative to the other causes the arms to move toward and away from each other.

6. An instrument according to claim 5, the inner of the two telescopic members being a toothed rod and the outer of the two telescopic members having a toothed wheel fixed thereto which engages the toothed rod for moving the two telescopic members relative to each other.

7. An instrument according to claim 6, including a releasable catch mounted on the outer of the telescopic members and engaging the teeth on the inner of the telescopic members for permitting free movement of the two telescopic members relative to each other in one direction but stopping movement of the two telescopic members relative to each other in the other direction.

8. An instrument according to claim 1, including two anchor screws securable to adjacent vertebrae, the frame member having a pair of arms, each arm having a tube encircling at least in part one of the anchor screws.

9. An instrument according to claim 8, wherein the retaining structure engages the rear end of its anchor screw and tightly engages the rear end of the tube.

10. An instrument according to claim 9, wherein the connecting member comprises two telescopic members, one arm connected to each of said telescopic members, such that telescopic movement of one of the telescopic members relative to the other causes the arms to move toward and away from each other.

11. An instrument according to claim 10, including a releasable catch mounted on the outer of the telescopic members and engaging the teeth on the inner of the telescopic members for permitting free movement of the two telescopic members relative to each other in one direction but stopping movement of the two telescopic members relative to each other in the other direction.

12. An instrument according to claim 1, the connecting member being a bar member, the two arms movable along the bar.

13. (Withdrawn) An instrument according to claim 1, including three anchor screws securable to three adjacent vertebrae, the frame member having three arms, each having a tube engaging one of the anchor screws.

14. (Withdrawn) An instrument according to claim 13, wherein the retaining structure comprises a threaded nut which threadedly engages the rear end of the anchor screw.

19. (Withdrawn) An instrument according to claim 1, wherein the retaining structure is a non-threaded securing structure.

20. (Withdrawn) An instrument according to claim 19, wherein the non-threaded securing structure is a resilient cap.

21. (Withdrawn) An instrument according to claim 19, wherein the non-threaded securing structure is a bayonet-type joint.

22. An instrument for spreading at least two adjacent vertebrae and/or retaining at least two adjacent vertebrae in a spaced apart condition, comprising:

a plurality of anchor screws, each having a forward end securable to a vertebrae,  
a frame member comprising at least two arms and a connecting member  
operatively connecting said two arms for movement toward and away from each other,  
each of said arms having an engaging structure operatively engagable with one of said  
anchor screws,

each arm further including a retaining structure operatively securing the engaging  
structure of each arm with its respective anchor screw to essentially prevent movement  
of that anchor screw relative to its engaging structure.

23. An instrument according to claim 22, wherein the engaging structure of each arm includes a part encircling its respective anchor screw.

24. An instrument according to claim 23, wherein the retaining structure engages its respective anchor screw on the side of the encircling part remote from the vertebrae.

25. An instrument according to claim 24, said retaining structure being a threaded nut engagable with a threaded part of the anchor screw.
26. (Withdrawn) An instrument according to claim 24, said retaining structure being a bayonet joint.
27. (Withdrawn) An instrument according to claim 24, said retaining structure being a resilient cap.
28. (Withdrawn) An instrument according to claim 24, wherein the end of each anchor screw remote from its engagement with its vertebrae is located in a recess formed in the top of its respective encircling part and the retaining structure is also located in said recess.
29. An instrument according to claim 22, wherein the retaining structure engages its anchor screw at an end thereof opposite from its end connected to the vertebrae.
30. An instrument according to claim 29, said retaining structure being a threaded nut engagable with a threaded part of its anchor screw.
31. (Withdrawn) An instrument according to claim 29, said retaining structure being a bayonet joint.

32. (Withdrawn) An instrument according to claim 29, said retaining structure being a resilient cap.

33. An instrument according to claim 22, wherein the connecting member comprising a connecting bar having two telescopic members, one arm connected to each of said telescopic members, such that telescopic movement of one of the telescopic members relative to the other causes the arms to move towards and away from each other.

34. An instrument according to claim 22, including two anchor screws securable to adjacent vertebrae, the frame member having a pair of arms, each arm having an engaging structure engaging one of said anchor screws.

35. (Withdrawn) An instrument according to claim 22, including three anchor screws securable to three adjacent vertebrae, the frame member having at least three arms, each arm having an engaging structure engaging one of the anchor screws.

**IX. EVIDENCE APPENDIX**

NOT APPLICABLE

**X. RELATED PROCEEDINGS APPENDIX**

NOT APPLICABLE